

NFL Biosciences: 2022 full-year business and earnings update

Phase II/III clinical trial for the drug candidate NFL-101 for smoking cessation: 100% of volunteers recruited. Initial results expected in the fourth quarter of 2023

Progress with the PRECESTO clinical trial to demonstrate the potential complementarity of NFL-101 with other smoking cessation treatments: final recruitment in the second quarter and initial results expected in the third quarter of 2023

Co-development agreement continuing to move forward for NFL-301, a drug candidate to reduce alcohol consumption

Intellectual property extended with a patent granted in China and South Korea and a new patent application submitted in the United States

Diversified sources of financing set up at the start of 2023: cash runway to the third quarter of 2024

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is reporting its full-year results for 2022, as approved by the Board of Directors on April 24, 2023. At this time, NFL Biosciences looks back on its many areas of progress for its drug candidates and the success of its financing strategy, with cash requirements covered through to the third quarter of 2024.

Ignacio Faus, NFL Biosciences Chairman of the Board and Chief Executive Officer: *“We are proud to announce the completion of the recruitment of the 318 volunteers taking part in our most important clinical study with NFL-101 for smoking cessation. The study, code-named CESTO II, was put in place following our initial public offering on Euronext Growth Paris in July 2021. The many advances made since this transaction contributed to the success of the €3.1m fundraising round carried out in January 2023, while also enabling us to obtain non-dilutive financing with public organizations supporting research in France. Our financial position is therefore secured through to the third quarter of 2024 and we can confidently continue, to develop our two priority drug candidates, NFL-101 and NFL-301. The coming quarters will of course be decisive for assessing the efficacy of NFL-101, with the initial results expected by the end of the year. We are moving forward with confidence into a key scientific period, in order to execute our business plan”.*

Phase II/III clinical trial for the drug candidate NFL-101 for smoking cessation: 100% of volunteers recruited and initial results planned for the fourth quarter of 2023

Approved in France by the French National Agency for the Safety of Medicines and Health Products (ANSM), the NFL-101 CESTO II Phase II/III clinical trial received a favorable opinion from the French Ethical Review Board (CPP) in September 2021. NFL-101 is a standardized version for pharmaceutical use derived from a natural product, initially developed by the Institut Pasteur for tobacco allergies among people working in tobacco factories. CESTO II's objectives are to select the best dose and assess the efficacy of NFL-101 versus placebo, based on various primary and secondary criteria set by the Food & Drug Administration (FDA) for the United States and the European Medicines Agency (EMA) for Europe.

Patient recruitment started in January 2022, gradually mobilizing a total of eight Clinical Investigation Centers (CIC) at CHU university hospital centers (Bordeaux, Clermont-Ferrand, Dijon, Lorient, Marseille, Montpellier, Poitiers and Rennes), as well as the Eurofins-Optimed research institute (Grenoble). The final recruitments were completed by the end of April 2023.

In terms of funding for CESTO II, NFL Biosciences was awarded a €1,500,000 innovation advance on February 20, 2023 under Programme d'Investissement d'Avenir 4 from the France 2030 plan. €1.05 million was received as a recoverable advance when the financing contract was signed, with the balance to be made available when requested by NFL Biosciences upon completion of the study. In addition, around 55% of the €3.1m of funds raised on January 31, 2023 has been allocated to finalizing this Phase II/III clinical trial. Together, these resources will make it possible to finalize the CESTO II study.

Progress with the PRECESTO clinical trial to demonstrate the potential complementarity of NFL-101 with other smoking cessation treatments

In September 2022, NFL Biosciences obtained the necessary regulatory authorizations from the ANSM and CPP to carry out the PRECESTO phase IIa clinical trial. Its main objective is to validate the potential complementarity of NFL-101 with other smoking cessation treatments, and particularly nicotine substitutes (transdermal patches, tablets, gum, inhalers and nicotine sprays), with a view to developing an innovative treatment method combining NFL-101 with other smoking cessation methods. The PRECESTO study targets 34 smokers who do not wish to quit and have high smoking satisfaction. It compares the ability of NFL-101 to reduce cigarette satisfaction and craving with placebo.

Volunteer recruitment started up in February 2023 and is still underway. The initial results are expected for the third quarter of 2023. This study could increase the attractiveness of NFL-101 to pharmaceutical companies, especially those marketing smoking cessation drugs.

In terms of funding for PRECESTO, NFL Biosciences was awarded a €200,000 grant (non-refundable) on January 17, 2023 under Programme d'Investissement d'Avenir 4 from the France 2030 plan, awarded jointly by the French State and the Occitanie Region. In addition, around 20% of the €3.1m of funds raised on January 31, 2023 have been allocated to carrying out this Phase IIa clinical trial. Together, these resources will make it possible to finalize the PRECESTO study, which is based on a format and protocol that limits the costs involved.

Co-development agreement continuing to move forward for NFL-301, a drug candidate to reduce alcohol consumption

In February 2022, NFL Biosciences set up a co-development agreement with ATHENA Pharmaceutiques, a market leader for the development and manufacturing of oral delivery drugs, to develop and produce NFL-301, a natural drug candidate from NFL Biosciences aimed at reducing alcohol consumption. The development of the formulation was launched during the first quarter of 2022. Under this partnership, ATHENA Pharmaceutiques will manage the development and manufacturing of NFL-301, while NFL Biosciences will draw up and lead the clinical program, which is expected to be launched in the United States over the coming months. The partnership aims to develop NFL-301 at least until its placebo-controlled efficacy has been demonstrated as a treatment for reducing alcohol consumption.

For the advancement of the NFL-301 project, from product formulation to clinical trial authorization, NFL Biosciences obtained a €200,000 innovation advance as part of Programme d'Investissement d'Avenir 4 from the France 2030 plan. €140,000 was received as a recoverable advance when the support contract was signed on February 20, 2023, with the balance to be made available when requested by NFL Biosciences upon authorization of the clinical trial. In addition, by allocating around 15% of the funds raised on January 31, 2023 to this project, NFL Biosciences will be able to continue developing NFL-301 and file a pre-IND application with the FDA prior to a future clinical trial application.

Intellectual property extended with a patent registered in China and South Korea and a new patent application submitted in the United States

NFL Biosciences has continued moving forward with its intellectual property management and patent protection strategy, securing exclusive rights to its drug candidate NFL-101 through two patent families, covering an "aqueous extract of tobacco leaves and its use for the treatment of dependence". The innovation that NFL-101 is based on is already protected through to 2036 in France and the United States, in addition to China (since April 2022) and South Korea (since May 2022). National registration applications are still in the review phase in the following regions and countries: Canada, Australia, Europe, Brazil, India, Indonesia, Philippines, United Arab Emirates and Nigeria.

In addition, a new patent application, corresponding to a third patent family, was submitted in October 2022 in the United States and will be extended to cover other countries in line with the intellectual property protection strategy put in place. This application aims to protect the administration of NFL-101 in association with other smoking cessation treatments and particularly nicotine substitutes.

Partnership with Themis Medicare to develop NFL-101 in India

In October 2022, NFL Biosciences set up a partnership with Themis Medicare Ltd to develop NFL-101 on the Indian market. Themis Medicare is a pharmaceutical company headquartered in Mumbai with a legacy of over 50 years of making new treatment options available to patients. India has approximately 267 million smokers, and their options for smoking cessation are very limited.

Diversified sources of financing set up at the start of 2023: cash requirements covered through to the third quarter of 2024

At the start of 2023, NFL Biosciences successfully rolled out its financing strategy by applying for various grants and cash advances, and by calling on the financial markets. In total, €4.2m were received during the first quarter of 2023 and €0.7m are still to be received as findings are generated confirming the success of the trials, representing a total secured amount of €4.9m. This has enabled NFL Biosciences to secure progress of the company's priority projects, and it has a cash horizon that now runs through to the third quarter of 2024.

Collaboration with the CEA to study the mechanism of action of NFL-101

At the start of February 2023, NFL Biosciences set up a research partnership with the French Alternative Energies and Atomic Energy Commission (CEA) to study the mechanism of action of its drug candidate NFL-101. This study, scheduled to run for nine months, is being led by the CEA's Paris-Saclay Pharmacological Neuroimaging team. It will focus on following, by positron emission tomography (PET) imaging, the modifications in the cerebral function associated with the development of tobacco addiction in mice, in order to highlight the central effects of NFL-101 treatment.

Governance changes

NFL Biosciences' Board of Directors acknowledged Mr Joël Besse's resignation from his positions as a Company director and Chairman of its Board of Directors on February 27, 2023. The Board of Directors decided to appoint Mr Ignacio Faus, the Company's Chief Executive Officer, as Chairman of the Board of Directors for a period that will not exceed his term of office as a director, i.e. through to the end of the General Meeting held in 2024 to approve the financial statements for the year ending December 31, 2023.

2022 full-year earnings

The full-year financial statements for 2022 (January 1 2022 – December 31, 2022), prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on April 24, 2023. The procedures to audit the annual accounts have been completed. The statutory auditors' reports will be issued when the 2022 Annual Report is published.

Corporate accounts (€)	December 31, 2021	December 31, 2022
Net revenues	-	-
Total operating income	39	22
EBIT	(901,867)	(3,083,170)
Financial income (expense)	(217,643)	182,831
Non-recurring income (expense)	-	39,025
Net income	(978,243)	(2,443,484)
Shareholders' equity	3,287,481	843,996
Intangible assets (patents)	124,034	135,784
Liabilities	270,749	1,478,510
- Of which financial liabilities	85,007	83,256
- Of which operating liabilities	185,742	1,395,254
Cash and cash equivalents	3,039,570	1,053,581
Balance sheet total	3,685,207	2,395,484

In 2022, NFL Biosciences recorded €22 of operating income, compared with €39 in 2021. Still in the clinical trials development stage, NFL Biosciences did not record any revenues during the last two years.

In line with the resources allocated to drive progress with the programs presented above, and the Company's operations, EBIT came to €(3.1)m in 2022, compared with €(0.9)m in 2021. Payroll and social security contributions totaled €0.7m for four people at December 31, 2022, compared with €0.3m for three people at the end of 2021.

In 2022, NFL Biosciences reported a research tax credit (CIR) of €0.4m, compared with €0.1m in 2021, with this change reflecting the ramping up of its research programs.

Financial income and expenses for 2022 totaled €0.2m, compared with €(0.2)m in 2021, reflecting the reversal of the provision for the NFL Australia receivables recorded in the accounts in 2021, following the completion of the process to shut this entity down. As a result, NFL Biosciences recorded €(2.4)m of net income, compared with €(1.0)m in 2021.

As of December 31, 2022, the Company had €0.8m of shareholders' equity and €1.0m of cash. The total amount of liabilities at December 31, 2022 came to €1.5m, with €0.1m of financial liabilities and €1.4m of operating liabilities. These cash and liability figures do not take into account the various financing facilities set up in 2023 as presented above.

Outlook for 2023

The initial results from the two clinical studies underway are expected to be available in the third quarter of 2023 (PRECESTO) and the fourth quarter of 2023 (CESTO II). Alongside this, NFL Biosciences has submitted a request for scientific advice to the EMA with a view to determining the future development of NFL-101 before its marketing authorization. This scientific advice will be issued in the second quarter of 2023. NFL BIOSCIENCES has also opened talks with several pharmaceutical companies looking into a future partnership for NFL-101. Once the PRECESTO and CESTO II results have been obtained, these discussions could be accelerated.

The collaboration with CEA Paris-Saclay, which aims to make progress with the understanding of the mechanism of action of NFL-101, will continue moving forward in 2023. Understanding NFL-101's mechanism of action is considered to be a very important element for several pharmaceutical companies.

Lastly, for NFL-301, the collaboration with ATHENA Pharmaceutiques is moving forward in line with the action plan. As the priority of this project is in the American market, discussions will be launched in 2023 with the FDA to clearly define the clinical development pathway. Non-dilutive financing options in the United States could then be available.

NFL BIOSCIENCES has a cash horizon through to the third quarter of 2024 and will continue to benefit from an organization with limited fixed costs. Looking further ahead, NFL Biosciences will need additional financing which, independently or combined, may come from (1) capital increases, (2) non-dilutive financing and (3) partnerships with pharmaceutical companies.

Next financial date: 2023 first-half earnings: September 19, 2023 (before start of trading).

About NFL Biosciences

NFL Biosciences is a biopharmaceutical company based in the Montpellier area which develops botanical drug candidates for the treatment of addictions. NFL Biosciences' ambition is to bring new, natural, safer and more effective therapeutic solutions to the entire world population, including low- and middle-income countries. Its most advanced product, called NFL-101, is a standardized, nicotine free tobacco leaf extract protected by two patent families. NFL Biosciences intends to offer smokers who want to quit a natural, safe, easy-to-administer and personalized alternative. NFL Biosciences is also developing NFL-301, a natural drug candidate for the reduction of alcohol consumption and has a drug development project for the treatment of cannabis use disorder.

The shares of NFL Biosciences are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL). Find out more at www.nflbiosciences.com

Contacts

Bruno Lafont – info@nflbiosciences.com - +33 4 11 93 76 67

Agence Calyptus – nflbiosciences@calyptus.net - +33 1 53 65 68 68